

Food and Drug Administration, HHS

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(B) *Indications for use.* As in paragraph (e)(3)(i) of this section.

(C) *Limitations.* Feed a total of 5 mg of fenbendazole per kg (2.27 mg/lb) of body weight to cattle over a 3- to 6-day period. Retreatment may be needed after 4 to 6 weeks. Cattle must not be

slaughtered within 13 days following last treatment. For dairy cattle the milk discard time is zero hours. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(4) Horses.

Amount fenbendazole in grams per ton	Indications for use	Limitations	Sponsor
(i) 4,540	5 mg/kg body weight (2.27 mg/lb) for the control of large strongyles (<i>Strongylus edentatus</i> , <i>S. equinus</i> , <i>S. vulgaris</i> , <i>Triodontophorus</i> spp.), small strongyles (<i>Cyathostomum</i> spp., <i>Cylicocyclus</i> spp., <i>Cylicostephanus</i> spp.), and pinworms (<i>Oxyuris equi</i>); 10 mg/kg body weight (4.54 mg/lb) for the control of ascarids (<i>Parascaris equorum</i>)..	Feed at the rate of 0. 1lb of feed per 100 lb of body weight to provide 2.27 mg fenbendazole/lb of body weight in a 1-day treatment or 0.2 lb of feed per 100 lb of body weight to provide 4.54 mg fenbendazole/lb of body weight in a 1-day treatment. All horses must be eating normally to ensure that each animal consumes an adequate amount of the medicated feed. Regular deworming at intervals of 6 to 8 weeks may be required due to the possibility of reinfection. Do not use in horses intended for human consumption..	000061
(ii) [Reserved]

(5) Zoo and wildlife animals.

Species/Class	Amount fenbendazole	Indications for use	Limitations	Sponsor
(i) Feral swine (<i>Sus scrofa</i>).	3 mg/kg/day for 3 days..	For the removal and control of kidney worm (<i>Stephanurus dentatus</i>), roundworm (<i>Ascaris suum</i>), nodular worm (<i>Oesophagostomum dentatum</i>).	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061
(ii) Ruminants (subfamily Antilopinae, Hippotraginae, Caprinae).	2.5 mg/kg/day for 3 days..	For the removal and control of small stomach worm (<i>Trichostrongylus</i> spp.), thread necked intestinal worm (<i>Nematodirus</i> spp.), barberpole worm (<i>Haemonchus</i> spp.), whipworm (<i>Trichuris</i> spp.).	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061
(iii) Rocky mountain bighorn sheep (<i>Ovis c. canadensis</i>).	10 mg/kg/day for 3 days..	For the removal and control of <i>Protostrongylus</i> spp.	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061

[66 FR 58935, Nov. 26, 2001, as amended at 68 FR 34534, June 10, 2003; 72 FR 66046, Nov. 27, 2007; 73 FR 58873, Oct. 8, 2008; 74 FR 61517, Nov. 25, 2009]

§ 558.261 Florfenicol.

(a) *Specifications.* Type A medicated articles containing florfenicol in the following concentrations:

(1) 40 grams per kilogram for use as in paragraph (e)(1) of this section.

(2) 500 grams per kilogram for use as in paragraph (e)(2) of this section.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Special considerations*—(1) Federal law limits this drug to use under the professional supervision of a licensed veterinarian. See § 558.6 of this chapter for additional requirements.

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(2) The expiration date of veterinary feed directives (VFDs) for florfenicol medicated feeds:

(i) For freshwater-reared finfish, must not exceed 15 days from the date of issuance.

(ii) For swine must not exceed 90 days from the date of issuance.

(3) VFDs for florfenicol shall not be refilled.

(d) *Related tolerances.* See § 556.283 of this chapter.

(e) *Conditions of use—(1) Swine—*

Florfenicol in grams/ton of feed	Indications for use	Limitations
182	For the control of swine respiratory disease (SRD) associated with <i>Actinobacillus pleuropneumoniae</i> , <i>Pasteurella multocida</i> , <i>Streptococcus suis</i> , and <i>Bordetella bronchiseptica</i> in groups of swine in buildings experiencing an outbreak of SRD..	Feed continuously as a sole ration for 5 consecutive days. The safety of florfenicol on swine reproductive performance, pregnancy, and lactation have not been determined. Feeds containing florfenicol must be withdrawn 13 days prior to slaughter.

(2) *Fish—*

Florfenicol in grams/ton of feed	Indications for use	Limitations
(i) 182 to 2,724	Catfish: For the control of mortality due to enteric septicemia of catfish associated with <i>Edwardsiella ictaluri</i> .	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 milligrams (mg) florfenicol per kilogram (kg) of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. A dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.
(ii) 182 to 1,816	Freshwater-reared salmonids: For the control of mortality due to coldwater disease associated with <i>Flavobacterium psychrophilum</i> and furunculosis associated with <i>Aeromonas salmonicida</i> .	Feed as a sole ration for 10 consecutive days to deliver 10 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.
(iii) 182 to 2,724	Freshwater-reared finfish: For the control of mortality due to columnaris disease associated with <i>Flavobacterium columnare</i> .	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 mg florfenicol per kg of fish for freshwater-reared warmwater finfish and 10 mg florfenicol per kg of fish for other freshwater-reared finfish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. For catfish, a dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.

Florfenicol in grams/ton of feed	Indications for use	Limitations
(iv) 273 to 2,724	Freshwater-reared warmwater finfish: For the control of mortality due to streptococcal septicemia associated with <i>Streptococcus iniae</i> .	Feed as a sole ration for 10 consecutive days to deliver 15 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. For catfish, a dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.

[70 FR 70047, Nov. 21, 2005, as amended at 71 FR 70304, Dec. 4, 2006; 72 FR 19798, Apr. 20, 2007; 72 FR 65885, Nov. 26, 2007; 77 FR 32012, May 31, 2012]

§ 558.265 Halofuginone hydrobromide.

(a) *Specifications.* Type A medicated articles containing 6 grams of halofuginone hydrobromide per kilogram.

(b) *Approvals.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.308 of this chapter.

(d) *Conditions of use.* (1) It is used in feed for broiler chickens as follows:

(i) *Amount.* 2.72 grams per ton.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(B) *Limitations.* Feed continuously as sole ration; withdraw 4 days before slaughter; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(ii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus bambarmycins 1 to 2 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 5 days before slaughter; do not feed to layers.

(iii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus virginiamycin 5 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for

increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 6 days before slaughter; do not feed to layers.

(iv) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus virginiamycin 5 to 15 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain.

(B) *Limitations.* Feed continuously as sole ration; withdraw 6 days before slaughter; do not feed to layers.

(v) *Amount per ton.* Halofuginone hydrobromide 2.72 grams (0.0003 percent) plus bacitracin methylene disalicylate 10 to 50 grams and roxarsone 22.7 to 45.4 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain; and for improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 5 days before slaughter; use as sole source of organic arsenic; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(vi) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus bacitracin methylene disalicylate 10 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, *E. maxima* and for improved feed efficiency.